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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,772	07/12/2001	Masahiro Iwamoto	46124-5001-01	1361

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EXAMINER	
SCHNIZER, HOLLY G	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,772	IWAMOTO ET AL.	
	Examiner	Art Unit	
	Holly Schnizer	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In view of the Amendment after Final rejection filed on May 21, 2004 and upon reconsideration, PROSECUTION IS HEREBY REOPENED. Upon reconsideration of the Specification in light of the new claims a new ground of rejection is set forth below.

The Amendment filed May 21, 2004 has been entered. Claims 1-33 and 35-39 have been cancelled. Claim 34 is pending and has been considered in this Office Action.

Rejections Withdrawn

The amendment overcomes the rejection under 35 U.S.C. 112, first paragraph for lack of enablement. Claim 34 was amended to delete the intended use as a "pharmaceutical" and the Specification indicates that the compositions containing the C-11 cDNA can be used to express the protein in vitro.

The amendment overcomes the rejection under 35 U.S.C. 102(b) as being anticipated by Dhordain et al. since claim 32 was cancelled.

Upon review of the specification, new issues concerning claim 34 have come to the examiners attention and are discussed below. Since these issues were not addressed previously, prosecution has been reopened and the present Office Action has been made non-final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon review of the present Specification, it appears that only a single C-11 cDNA is described. Examples 1-2 describe the isolation of the C-11 cDNA. The Specification only describes the translated region of the gene and not the entire gene and gene sequence. A gene is considered to comprise essential elements such as particular introns, promoters, splice donors/acceptor sites, that require specific support. These elements vary depending on the cell in which the gene is expressed (for example the regulatory elements and untranslated regions of a gene in the brain may differ from the regulatory elements and untranslated regions of the same gene in the liver). In the present case, the Specification does not describe any of these elements of the C-11 gene or identify the cell from which the "gene" is isolated.

The disclosed distinguishing identifying characteristics include a partial structure (the sequence of the C-11 protein encoding sequence) and the function associated with that structure (cell calcification inhibition). However, there is no known or disclosed

correlation between this function and the structure of the non-described regulatory elements and untranslated regions of the gene. Furthermore, there is no additional disclosure of the physical and/or chemical properties of the regulator elements or untranslated regions. Thus, one skilled in the art would not recognize from the present disclosure that applicant was in possession of the genus of C-11 genes.

In addition, the specification only provides one sequence for the C-11 cDNA. This single sequence is insufficient to describe the entire genus of C-11 genes or C-11 cDNAs because it does not provide one with the knowledge of what sequences other than the disclosed sequence are considered "C-11 genes" or C-11 cDNAs. The Specification discloses that the C-11 cDNA disclosed is associated with cell calcification inhibition. However, the Specification does not disclose any correlation between structure and function to allow one of skill in the art to recognize variants of the disclosed sequence that would maintain that function. Thus, one skilled in the art would not recognize from the present disclosure that applicant was in possession of the genus of C-11 genes or C-11 cDNAs other than the specific nucleotide sequence disclosed or sequences that encode the specific amino acid sequence disclosed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 34 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 of U.S. Patent No. 6,294,354. An obviousness type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F. 3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are patentably distinct from each other because claim 34 is generic to all that is recited in claims 1-2 of U.S. Patent No. 6,294,354. That is, claims 1-2 of U.S. Patent No. 6,294,354 fall entirely within the scope of claim 34, or Claim 34 is anticipated by Claims 1-2 of U.S. Patent No. 6,294,354. Specifically, the nucleic acid encoding a C11 protein of claim 1 and the nucleotide sequence of claim 2 of the patent is the "C11 gene" as described in the present specification and claimed in claim 34.

The examiner is aware that a previous rejection of claim 34 for double patenting over U.S. Patent No. 6,294,354 was overcome by Applicants arguments in the Response filed July 15, 2003 indicating that a restriction in parent Application No.

08/878,177 mailed 10/26/98, separated the nucleic acids from the pharmaceutical compositions. However, the restriction notes that the two groups were separated based on the intended use of the compositions in gene therapy. The present claims differ from the pharmaceutical compositions since they encompass compositions for in vitro use of the nucleic acids.

Conclusions

No Claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Monday-Wednesdays from 8 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Holly Schnizer
June 2, 2004

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